510(k) SUMMARY

NOV 19 2009

Submitter's name: Advanced Vascular Dynamics Division
dba Advanced Vascular Dynamics/ClampEase
1910 NW 23rd Place, Portland, OR 97210

Contact name and address: Matthew Semler, President
503-223-2333

Date summary prepared: August 11, 2009

Device name:

Proprietary name:	RADAR™ Vascular Compression Devices
Common or usual name:	Vascular compression device
Classification name:	Vascular clamp (870.4450). Vascular clamp (74 DXC).

Legally marketed device for substantial equivalence comparison:

The predicate devices for this submission are the TR Band submitted by Terumo Medical Corp. and cleared for marketing under 510(k) #K070423 and the Comfort-Band submitted by TZ Medical and cleared under 510(k) #K040208.

Description of the device:

The RadAR™ Vascular Compression Devices are compression devices used on the arm. Each device consists of a strap with a housing, a screw permanently inserted into the housing, and a movable compression pad. The product is designed to reduce blood flow in the blood vessel compressed by the pad while allowing blood flow in other vessels in the arm. The user can delicately control the compression applied by the device without unfastening it. This allows gradual release of compression as hemostasis occurs and, at the user's discretion, permits blood flow in the compressed vessel during puncture site hemostasis. The product is provided individually packaged. It is a sterile, single-use device.

Intended use of device:

The RadAR™ Vascular Compression Devices are indicated for use by medical professionals to promote hemostasis following a catheterization or other puncture into a blood vessel in a patient's arm, including radial artery catheterization, arterial or venous line removal, hemodialysis, and in patients on anticoagulation therapy.

Technological characteristics:

The device features of the RadAR™ Vascular Compression Devices and the predicate devices are very similar. All three products have an adjustable strap and apply pressure to the puncture site in the patient's arm. There are some design variations, but these do not affect the substantial equivalence of the RadAR.

Testing conducted:

Sterilization, biocompatibility, functional, and performance testing were conducted on sterilized RadAR devices by third parties in June, July and August of 2009. The RadAR devices successfully passed all tests.

Performance testing:

Comparative performance testing and clinical evaluations were not submitted as part of this 510(k).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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Advanced Vascular Dynamics
c/o Mr. Matthew Semler
President
1910 NW 23rd Place
Portland, OR 97210

Re: K092503
Trade/Device Name: RadAR™ Vascular Compression Device
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II (two)
Product Code: DXC
Dated: November 9, 2009
Received: November 13, 2009

Dear Mr. Semler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092503

Device Name: RADAR™ Vascular Compression Devices

Indications for Use:

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K092503